

FORM PTO-1390  
(REV. 2-2005)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTORNEY'S DOCKET NUMBER  
10103-016-999 (CAM: 052922-999016)

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO.  
PCT/US2003/030407INTERNATIONAL FILING DATE  
September 25, 2003U.S. APPLICATION NO. (if known, see 37CFR 1.5)  
To be assigned**107529520**PRIORITY DATE CLAIMED  
September 27, 2002

## TITLE OF INVENTION

METHODS AND COMPOSITIONS FOR THE TREATMENT OF LUPUS USING CLOFARABINE

## APPLICANT(S) FOR DO/EO/US

WOOD, Christopher; SMITH, Stuart William Gordon

Applicant herewith submits to the United States Designated/ Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3.  This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4.  The U.S. has been elected (Article 31).
5.  A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a.  is attached hereto (required only if not communicated by the International Bureau).
  - b.  has been communicated by the International Bureau.
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US)
6.  An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a.  is attached hereto.
  - b.  has been previously submitted under 35 U.S.C. 154(d)(4).
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a.  are attached hereto (required only if not communicated by the International Bureau).
  - b.  have been communicated by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.  An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)) (unsigned).
10.  An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 20. below concern document(s) or information included:**

11.  An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.  A preliminary amendment.
14.  An Application Data Sheet under 37 CFR 1.76.
15.  A substitute specification.
16.  A power of attorney and/or change of address letter.
17.  A computer-readable form of the sequence listing in accordance with PCT Rule 13ter 2 and 37 CFR 1.821- 1.825.
18.  A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19.  A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
20.  Other items or information: International Search Report; International Preliminary Examination Report.

|  |                       |  |  |
|--|-----------------------|--|--|
| US APPLICATION NO. (If known, see 37 CFR 1.5)<br>To be assigned <b>107529520</b>   |                       | INTERNATIONAL APPLICATION NO.<br>PCT/US2003/030407                             | ATTORNEY'S DOCKET NUMBER<br>10103-016-999 (CAM: 052922-999016) |
| <p>21. The following fees are submitted:</p> <p><b>BASIC NATIONAL FEE:</b></p> <p><input checked="" type="checkbox"/> a) Basic national fee ..... <b>\$300.00</b></p> <p><input checked="" type="checkbox"/> b) Examination fee .....<br/>Was the International Preliminary Examination Report prepared by the USPTO and do all filed claims in this U.S. application satisfy provisions of PCT Article 33(1)-(4) (i.e., novelty, inventive step and industrial capability)? ....<br/> <input type="checkbox"/> i) Yes (\$100.00) .....<br/> <input checked="" type="checkbox"/> ii) No (\$200.00) ..... <b>\$200.00</b></p> <p><input checked="" type="checkbox"/> c) Search fee .....<br/>Was the USPTO the International Searching Authority? .....<br/> <input checked="" type="checkbox"/> i) Yes (\$100.00) .....<br/> ii) If no:<br/> <input type="checkbox"/> (a) An International Search Report will be provided to the USPTO on or before payment of the search fee. (\$400.00) .....<br/> <input type="checkbox"/> (b) No International Search Report will be provided to the USPTO. (\$500.00) ..... <b>\$100.00</b></p> |                       |  |  |
| <b>TOTAL OF CALCULATIONS =</b>   |                       |  |  |
| \$ <b>\$600.00</b>   |                       |  |  |
| <p><input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing of computer programs listing filed in electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.</p>  |                       |  |  |
| Total Sheets<br>32 -100  | Extra Sheets<br>0 /50 | Number of each additional 50 or fraction thereof (round up to a whole number). | RATE<br><b>x 250.00</b>  |
|  |                       |  | <b>\$0.00</b>  |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).  |                       |  |  |
| \$ <b>\$0.00</b>   |                       |  |  |
| CLAIMS   | NUMBER FILED          | NUMBER EXTRA   | RATE X   |
| Total Claims   | 19 - 20               | 0  | <b>x \$50.00</b>   |
| Independent Claims   | 4 - 3                 | 1  | <b>x \$200.00</b>  |
| <b>= \$200.00</b>  |                       |  |  |
| <p><input type="checkbox"/> MULTIPLE DEPENDENT CLAIM(S) (if applicable)</p>  |                       |  |  |
| <b>+ 360.00</b>  |                       |  |  |
| <b>TOTAL OF ABOVE CALCULATIONS=</b>  |                       |  |  |
| <b>= \$ 800.00</b>   |                       |  |  |
| <p><input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 50%</p>  |                       |  |  |
| <b>- \$ 400.00</b>   |                       |  |  |
| <b>SUBTOTAL =</b>  |                       |  |  |
| <b>\$ 400.00</b>   |                       |  |  |
| Surcharge of \$130.00 for furnishing the English Translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |                       |  |  |
| <b>\$0.00</b>  |                       |  |  |
| <b>TOTAL NATIONAL FEE</b>  |                       |  |  |
| <b>= \$ 400.00</b>   |                       |  |  |
| Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). 0 x \$40.00 per property  |                       |  |  |
| <b>\$ 0.00</b>   |                       |  |  |
| <b>TOTAL FEES ENCLOSED</b>   |                       |  |  |
| <b>= \$ 400.00</b>   |                       |  |  |
| <b>Amount to be refunded:</b>  |                       |  |  |
| <b>charged:</b>  |                       |  |  |
| <p>a. <input type="checkbox"/> A check in the amount of \$ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> This is an estimate of the fees due. Please charge Deposit Account No. 50-3013 to cover the required fees. A copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3013. A copy of this sheet is enclosed.</p>  |                       |  |  |
| <p><b>Note: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.</b></p>  |                       |  |  |
| <p>22. <input type="checkbox"/> Other instructions</p>   |                       |  |  |
| <p>23. <input checked="" type="checkbox"/> All correspondence for this application should be mailed to <b>JONES DAY 20583</b></p>  |                       |  |  |
| <p>24. <input checked="" type="checkbox"/> All telephone inquiries should be made to <b>Lawrence Graham Tel.: 858 314-1200</b></p>   |                       |  |  |
| Anthony M. Insogna   |                       | <i>Anthony M. Insogna S.D. Reg. # 49,020</i><br>NAME SIGNATURE REG. NO. 35,203 |  |
|  |                       | March 25, 2005 DATE  |  |

| US APPLICATION NO. (If known, see 37 CFR 1.1)  | INTERNATIONAL APPLICATION NO. | ATTORNEY'S DOCKET NUMBER  |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
|--|-------------------------------|---|-------------------|--------------|--------------|--------|--------------|---------|---|-----------|--------------------|-------|---|------------|--|--|--|-------------------|
| To be assigned <b>107529520</b>  | PCT/US2003/030407             | 10103-016-999 (CAM: 052922-999016)  |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| 21. The following fees are submitted:  |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
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| <b>TOTAL OF CALCULATIONS =</b>   |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| \$ <b>\$600.00</b>   |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing of computer programs listing filed in electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.   |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| Total Sheets   | Extra Sheets                  | Number of each additional 50 or fraction thereof (round up to a whole number) |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| 32 - 100   | 0 /50                         | <b>RATE</b>   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| <b>PROSTANT Date: 08/15/2005 WALVARAD</b><br><b>04/01/2005 GFREY1250.00000114 503013 10529520</b><br><b>02 FC-2633 100.00 CR</b>   |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).  |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| <table border="1" style="width: 100%;"> <thead> <tr> <th>CLAIMS</th> <th>NUMBER FILED</th> <th>NUMBER EXTRA</th> <th>RATE X</th> </tr> </thead> <tbody> <tr> <td>Total Claims</td> <td>19 - 20</td> <td>0</td> <td>x \$50.00</td> </tr> <tr> <td>Independent Claims</td> <td>4 - 3</td> <td>1</td> <td>x \$200.00</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td></td> <td>= <b>+ 360.00</b></td> </tr> </tbody> </table>                             |                               |   | CLAIMS            | NUMBER FILED | NUMBER EXTRA | RATE X | Total Claims | 19 - 20 | 0 | x \$50.00 | Independent Claims | 4 - 3 | 1 | x \$200.00 | <input type="checkbox"/> MULTIPLE DEPENDENT CLAIM(S) (if applicable) |  |  | = <b>+ 360.00</b> |
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| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
| \$ <b>\$800.00</b>   |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
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| <b>SUBTOTAL =</b>  |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
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| <b>Amount to be refunded:</b>  |                               |   |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |
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| Anthony M. Insogna <i>Anthony M. Insogna</i> Reg. # 49,020<br>NAME SIGNATURE   |                               | 35,203<br>REG. NO.<br>March 25, 2005<br>DATE                                  |                   |              |              |        |              |         |   |           |                    |       |   |            |  |  |  |                   |